REMARKS

Claims 52-85, 94, 100, 101 and 103-113 presently appear in this case. Claims 65-75 have been allowed. The remaining claims have been rejected. The official action of November 25, 2005, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to peptides derived from a domain that forms the central turn of a pyrogenic exotoxin, which peptide does not have toxin agonist activity and is capable of antagonizing toxin-mediated activation of T-lymphocytes.

Claims 103-111 and dependent claims 52-64 and 94 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed had possession of the claimed invention. The examiner explains that this is a new matter rejection. The examiner states that, as to SEQ ID NOs:13 and 14, set forth in claim 103, these sequences are directed to peptides consisting of 10 or 12 amino acids while applicants' specification is silent as to this length of a peptide with the motifs of KKK and QELD, as disclosed at page 26, lines 6-9. The examiner states that applicants are required to recite

clear support for all of these claimed limitations or cancel the newly added material. This part of the rejection is respectfully traversed.

That decamers and dodecamers are preferred embodiments of the present invention is clear from a reading of the present specification as a whole. Not only are the preferred embodiments of SEQ ID NOs:1 and 2 dodecamers and SEQ ID NOs:3 and 4 decamers (all of which have the KKK and QELD motifs of SEQ ID NOs:13 and 14), but also the specification, for example, at page 47, lines 3-12 and 21, indicate that preferred embodiments are dodecapeptides "such as p12(150-161) or pSEB(150-161)." The words "dodecamers" and "decamers" also appear at page 36, line 20. Thus, it is clear that, in general, peptides that are dodecamers or decamers are preferred in the present invention. Thus, the combination of the preferred parameters of size with the preferred parameters of KKK and QELD motifs is not something that is new matter, but it is something that those of ordinary skill in the art reading the present specification would understand was in the possession of the inventors at the time that the application was filed.

Furthermore, the specification discloses that the inventors were in possession of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4 "and functional derivatives thereof"

or "derivatives thereof." See page 20, lines 16 and 21, and page 21, lines 6-8, 15-16 and 20. The terms "derivatives" and "functional derivatives" are defined at page 19, lines 14-17, as meaning "peptides with any insertions, deletions, substitutions and modifications that are capable of eliciting protective immunity against toxic shock induced by the exotoxins and/or of antagonizing toxin-mediated activation of T cells." Thus, it is clear that the dodecapeptide and decapeptides of SEQ ID NOs:1-4 are preferred embodiments and include substitutions within the amino acid sequence thereof. The disclosure in the paragraph bridging pages 25 and 26 indicates that the preferred motifs shared by these peptides are the KKK and QELD motifs. Thus, it is clear that the inventors were in possession of the preferred decapeptides and dodecapeptides, as well as substitutions therein that maintain the KKK and QELD motifs. Thus, SEQ ID NOs:13 and 14 do not possess new matter, but merely define a preferred embodiment of the present invention, that the inventors were in possession of at the time the application was filed for the reasons discussed above. Reconsideration and withdrawal of this part of the rejection are, therefore, respectfully urged.

The examiner states that the disclosure in the sentence bridging pages 25 and 26 does not support SEQ ID NO:15 as this statement does not provide support for claiming

any peptide that has these conserved residues absent a clear statement that such molecules are intended to be claimed. Furthermore, the examiner states that the claimed peptide "consists" of a 12-amino acid fragment but applicants have not pointed to support for claiming fragments of such a size with the features recited by the claim. This part of the rejection is also respectfully traversed.

The statement in the sentence bridging pages 25 and 26 that supports SEQ ID NO:15 reads:

> Residues T150, K152, E159 and D161 of this SEB domain are conserved among all staphylococcal enterotoxins ... [emphasis added]

The reference to "this SEB domain" clearly refers to the domain "T N K K K V T A Q E L D" set forth at page 25, line 23, which is peptide pSEB(150-161). Thus, one is speaking of the four residues of this dodecamer domain of SEB. The importance of this disclosure of conservation of specific residues would be apparent to anyone of ordinary skill in the art trying to design functional derivatives of this SEB domain that will maintain the antagonist activity. Clearly then, functional derivatives of SEQ ID NO:1 that maintain the conserved residues T150, K152, E159 and D161 would be considered to be within the possession of the inventors by anyone of ordinary skill in the art reading the present

specification as a whole. Reconsideration and withdrawal of this part of the rejection are, therefore, respectfully urged.

Claims 100-102, 109-111, 52-64, 76-85 and 112-113 have been rejected under 35 U.S.C. §112, first paragraph, for failure to comply with the written description requirement. The examiner states that these claims recite a peptide having at least 25% homology with a peptide that does not have toxin agonist activity and is capable of antagonizing toxin-mediated activation of T-lymphocytes. The examiner states that the specification and claims do not indicate what distinguishing attributes are shared by the members of the genus and that the genus is highly variant. Thus, the language "25% homology" alone is insufficient to describe the genus. The examiner states that the disclosure fails to provide a representative number of species to describe the genus. This rejection is respectfully traversed.

Claim 100 has now been amended at paragraph b) to insert the subject matter of previously-appearing claim 102 therein, and claim 102 has been deleted. The examiner objected to the recitation of "a peptide having at least 25% homology with the peptide of a)" in claim 100. As amended, claim 100 no longer reads on analogs having a minimum of 25% homology. The analog of paragraph b) of claim 100 must be the

same as that of a), except having insertions, deletions or substitutions of up to three amino acids.

As amended, claim 100, paragraph b), does not suffer the same deficiencies as noted by the examiner for the language "at least 25% homology." The distinguishing attributes shared by the genus are effectively set forth in that all of the amino acids of the peptide are maintained except for up to three. Furthermore, the resultant peptide maintains the properties of not having toxin agonist activity and the capability of antagonizing toxin-mediated activation of T lymphocytes. This combination of structure and function is sufficient to satisfy the first paragraph of 35 U.S.C. §112. Furthermore, the present specification in the paragraph bridging pages 25 and 26 indicates that the 150-161 domain of SEB is highly conserved among pyrogenic toxins in general, with 10/12 identities for SEA, SEC1, SEC2, and SPEA and 9/12 for SEE. This is further evidence that changes of three or fewer amino acids from the natural sequence would not be expected to substantially affect the properties.

For all of these reasons, it is urged that the present amendment to claim 100 obviates this rejection. Reconsideration and withdrawal thereof are therefore respectfully urged.

Claims 100-102, 109-111, 52-64, 76-85 and 112-113 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement, this being a new matter rejection. The examiner states that the recitation "at least 25% homology" does not have support in the specification.

As the language alleged to be new matter no longer appears in the claims, this rejection has now been obviated. Reconsideration and withdrawal thereof are respectfully urged.

The examiner's indication of allowability of claims 65-75 is gratefully appreciated.

It is submitted that all of the claims now present in the case clearly define over the references of record and fully comply with 35 U.S.C. §112. Reconsideration and allowance are, therefore, earnestly solicited.

Respectfully submitted,

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